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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,672	03/30/2004	Theodore John Cole	VPI-001	3562
22506	7590	08/29/2007		
JAGTIANI + GUTTAG 10363-A DEMOCRACY LANE FAIRFAX, VA 22030			EXAMINER ARNOLD, ERNST V	
			ART UNIT	PAPER NUMBER
			1616	
			MAIL DATE	DELIVERY MODE
			08/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/812,672	Applicant(s) COLE ET AL.	
	Examiner Ernst V. Arnold	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1 and 3-25 are pending. Claims 23-25 are new.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/26/06 has been entered.

Withdrawn rejections/objections:

Claim 22 was objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1. Applicant has amended the claim to overcome this objection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 3-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In the instant case, claims 1 and 21 recite the limitation "a combination providing a therapeutic benefit". The instant

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specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without undue experimentation.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: 1) scope or breadth of the claims; 2) nature of the invention; 3) relative level of skill possessed by one of ordinary skill in the art; 4) state of, or the amount of knowledge in, the prior art; 5) level or degree of predictability, or a lack thereof, in the art; 6) amount of guidance or direction provided by the inventor; 7) presence or absence of working examples; and 8) quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure. When the above factors are weighed, it is the Examiner's position that one skilled in the art could not practice the invention without undue experimentation.

1) Scope or breadth of the claims

The claims recite "a combination providing a therapeutic benefit". The specification merely discloses, without more, that a naturally occurring element combination can provide or improve the physical energy, well-being and support of individuals and provide relief from various types of pains and aches such as muscle stiffness, headache, menstrual pain, sprain, inflammation, arthritis, carpal tunnel, bruises, broken bones and sports injuries (Page 3, [0008]). However, there is no evidence that the invention works as instantly claimed.

2) Nature of the invention

The nature of the invention is directed to an elemental combination for providing a therapeutic benefit and a method of providing vibrational therapy using the combination.

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3) Relative level of skill possessed by one of ordinary skill in the art

The relative level of skill possessed by one of ordinary skill in the art of medical research is relatively high, as a majority of lead investigators directing scientific research and development in this particular technological area possess an M.D. and/or a Ph.D. in a scientific discipline such as organic synthetic chemistry, medicinal chemistry, biochemistry, pharmacology, biology or the like.

4) State of, or the amount of knowledge in, the prior art

The therapeutic value of crystals is controversial in the art and there are not a sufficient number of reports available identifying the uses of crystal therapy (Aetna's inteliHealth featuring Harvard Medical School's consumer Health Information, Complementary & Alternative Medicine, Crystal Therapy, Electrocrystal Therapy 07/05/2005 page 2). With respect to the state of the art of science, a geology faculty member of Missouri State University stated: "In Science, the burden of proof always rests on the claimant and not on the skeptic. It is the responsibility of the claimant to bring forth clear and acceptable evidence (facts) to show that their claim is real." (Miller, 2006 page 3).

5) Level or degree of predictability, or a lack thereof, in the art

- The safety and effectiveness of these techniques have not been thoroughly tested scientifically. There is no evidence for this technique (Aetna's inteliHealth featuring Harvard Medical School's consumer Health Information, Complementary & Alternative Medicine, Crystal Therapy, Electrocrystal Therapy 07/05/2005 page 2).

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- From the Louisville School of Medicine: “Crystal therapy contradicts scientific understanding of anatomy, physiology, and/or biochemistry; or of basic principles of physics and chemistry. Scientific studies in support are weak or absent” (Wheeler, T. 2006; page 9).
- From a geology faculty member of Missouri State University: Crystal therapy is a pseudoscience and “pseudoscience is in business of selling you a wished for Universe whether it’s real or not” (Miller, 2006; pages 6 and 7). And; “All rely on faith, which can be defined as belief without evidence. Science requires belief to be based on evidence.” (Miller, page 7).
- From the British Medical Journal, Rees et al. state in an article on integrated medicine that there is no research evidence at all for crystal therapy (page 119, right column center).

6) Amount of guidance or direction provided by the inventor

Applicant was required to provide in the specification additional guidance and direction with respect to how use the claimed subject matter in order for the application to be enabled.

Applicant does not provide any guidance.

7) Presence or absence of working examples

The specification fails to provide any scientific data/evidence and working embodiments with respect to a combination providing any therapeutic benefit.

8) Quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure

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Applicant has not disclosed any working examples nor suggested the amount of material required, in what ratios, and for what duration they must be applied/administered to the patient in order to achieve a therapeutic benefit. It appears that one of ordinary skill in the art has been left in the dark as to how to practice the invention and has to figure it out for themselves. This is a daunting task especially when the art is skeptical about vibrational/crystal therapy as being beneficial. As a result, one of ordinary skill in the art would be required to conduct labor intensive trial and error experimentation with each and every combination in a myriad number of ratios of components for an unknown period of time, not to mention the preferred route of administration such as oral, topical, or rectal, on patients suffering from, for example, pain in order to ascertain if the combination had the desired therapeutic effect. Thus, one of ordinary skill in the art would have to conduct an undue amount of experimentation to reasonably and accurately determine whether the combination would provide any therapeutic benefit.

In conclusion, it is readily apparent from the aforementioned disclosure, in conjunction with a corresponding lack of scientific evidence and working embodiments regarding the therapeutic benefit of the combination, that one of ordinary skill in the art would therefore be required to conduct an undue amount of experimentation to reasonably and accurately extrapolate whether said combination would be therapeutically beneficial. *Genetech*, 108 F.3d at 1366 states that “a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion” and “patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable.” (Examiner emphasis added.)

Response to arguments:

Applicant asserts that the Examiner has improperly put the burden on Applicant to demonstrate that the invention works as instantly claimed and that the allegation must be based on the Examiner's personal knowledge. The Examiner cannot agree. MPEP 2164.04 states: In order to make a rejection, the examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. In re Wright, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993) (examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure). A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. Assuming that sufficient reason for such doubt exists, a rejection for failure to teach how to make and/or use will be proper on that basis. In re Marzocchi, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). (Examiner added emphasis) As stated by the court, "it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure." 439 F.2d at 224, 169 USPQ at 370.

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The Examiner has correctly doubted the objective truth by providing four citations, which clearly state that this is a controversial issue, that there are insufficient reports available and that there is no evidence for this technique. This provided the Examiner with sufficient doubt as to the enablement of the instant invention. Applicant asserts that the Examiner has failed to provide substantial evidence numerous times in the arguments when the Examiner has provided concrete published documents questioning the validity of the technique and Applicant has provided merely arguments in response. Applicant asserts that the therapeutic benefits are "generally accepted" in the art, namely US 6,014,973, US 6,143,946 and US 6,378,138. The Examiner reminds Applicant that examination is a case-by-case process. The Examiner has found art, which raises doubt to the enablement of the instant invention and has made a proper rejection. The nature of the invention is controversial as evidenced by the citations provided by the Examiner. The authors of the citations are doctoral level and hold positions at established universities and medical research centers thus supporting the Examiner's statement about the skill in the medical art. Applicant asserts that guidance and direction are provided. However nothing is provided by way of examples to support these assertions. Certainly, one can wear, ingest, and insert the instantly claimed combinations anywhere and anyhow they desire but to have a therapeutic benefit for a specific ailment is not disclosed.

In conclusion, the Examiner has now presented four pieces of art that doubt the validity of crystal/vibrational therapy as having any benefit whatsoever. The burden is properly placed on Applicant to demonstrate otherwise. The rejection is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 7-10, 16 and 18-22 remain/are rejected under 35 U.S.C. 102(b) as being unpatentable over Ridgley et al. (US 6,378,138) as evidenced by the as evidenced by the MAGS EXPLORER, Gemstones page 5.

Ridgley et al. disclose an article of clothing that incorporates various types of healing devices such as crystals for healing various bodily ailments (Abstract; column 1, lines 36-44; and claims 1-9). The healing elements include tourmaline, smoky quartz and pyrite, for example (For listing of elements see: column 2, line 18-column 4, line 15). Tourmaline is a complex borosilicate mineral with varying amounts of aluminum, iron, magnesium, sodium, lithium, potassium, and sometimes other elements, used as a gem. Red and pink tourmaline is known as rubellite thus reading on instant claim 1 and 21 (as evidenced by the MAGS EXPLORER, Gemstones page 5.). The naturally occurring elements are incorporated into the waistbands of stockings, hosiery and pantyhose as well as ankle bands hence reading on instant claims 7-9 and 11 (Column 24, lines 1-13 and column 5, lines 15-27). The Examiner interprets the ankle band as synonymous with ankle strap. Wearing the clothing places the combination of naturally occurring elements next to the body of the user, which would necessarily place the naturally occurring element combination in close proximity to the user; therefore reading on instant claims 16 and 18. Ridgley et al. disclose that the particular healing elements incorporated into the

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stocking would depend on the results desired and can vary as the element chosen, the affliction to be treated or the region of the body afflicted (Column 5, lines 36-40). The kits of instant claims 19 and 20 do not distinguish themselves from the disclosure of Ridgely et al. (See: *In re Ngai*, 367 F.3d 1336, 1339, 70 USPQ2d 1862, 1864 (Fed. Cir. 2004)).

Response to arguments:

Applicant continues to assert that Ridgely et al. do not teach any of the elements from Group 1 including rubellite. As evidenced by the MAGS EXPLORER, Gemstones page 5., another name for tourmaline is pink or red rubellite, which would be readily recognized to one of ordinary skill in the art. Applicant asserts that tourmaline and rubellite are entirely different gemstones and that Wikipedia cannot be relied upon. The Examiner cannot agree. Applicant has merely provided arguments that rubellite and tourmaline are entirely different gemstones without any factual evidence. The Examiner maintains his position.

Claim Rejections - 35 USC § 102

Claims 1, 7, 16 and 18-22 remain/are rejected under 35 U.S.C. 102(b) as being anticipated by Untracht, O. Jewelry Concepts and Technology New York 1982, pages 510 and 601 as evidenced by the MAGS EXPLORER, Gemstones page 5.

Untracht discloses jewelry made from silver and tourmaline and gold and tourmaline (see page 510 11-55 and page 601 13-47, for example). As evidenced by the MAGS EXPLORER, Gemstones, rubellite is merely pink to red tourmaline, which would be readily recognized to one of ordinary skill in the art (page 5 of 6). It is the Examiner's position that any therapeutic benefit provided by the combination is inherent in the combination. "A chemical composition and its

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properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. (*In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990)). The kits of instant claims 19 and 20 do not distinguish themselves from the disclosure of Untracht (See: *in re Ngai*, 367 F.3d 1336, 1339, 70 USPQ2d 1862, 1864 (Fed. Cir. 2004)).

Response to arguments:

Applicant asserts that tourmaline and rubellite are entirely different gemstones and that Wikipedia cannot be relied upon. The Examiner cannot agree. Rubellite is merely a red tourmaline as evidenced by the MAGS EXPLORER, Gemstones page 5. Applicant has merely provided arguments that rubellite and tourmaline are entirely different gemstones without any factual evidence.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3-11 and 19-25 remain/are rejected under 35 U.S.C. 103(a) as being unpatentable over Untracht, O. Jewelry Concepts and Technology New York 1982.

Applicant claims a combination providing a therapeutic benefit comprising naturally occurring elements in amounts ranging from about 1 part to about 10 parts from each of the groups and devices associated with the combination, which are a strap, clothing or furniture and kits including the combination.

Determination of the scope and content of the prior art

(MPEP 2141.01)

The reference of Untracht is discussed above and that discussion is hereby incorporated by reference.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Untracht does not expressly teach the specific amounts of the naturally occurring elements in the combination or devices associated with the combination, which are a strap, clothing or furniture and kits including the combination or providing vibrational therapy to a patient in need of such therapy.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make the naturally occurring element combinations in the amounts of from 1 to about 10 parts and the narrower range of about 1 to about 2 parts and make devices associated with the combination, which are a strap, clothing or furniture and kits including the combination and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because in the art of making jewelry one of ordinary skill in the art is inclined to mix and match various naturally occurring elements to create various combinations as shown in Untracht. It is the Examiner's position that one of ordinary skill in the art can mix and match any naturally occurring elements in any ratio to produce such combinations. The adornment of straps, clothing, and furniture is a reasonable extension of the artisan to decorate items for market. Persons wearing the adornments taught in Untracht would benefit from wearing the combination of materials, and receive any vibration therapy therefrom, because the benefit is intrinsic to wearing them, in the absence of evidence to the contrary.

In the absence of any criticality/unexpected results, the presently claimed invention is considered prima facie obvious over the prior art for the reasons of record and those stated above.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to arguments:

Applicant asserts that it must be the Examiner's personal knowledge that the art reference of Untracht renders claims 4-10 obvious. The Examiner cannot agree. In figure 11-55 of Untracht, there are multiple tourmaline stones in the silver necklace. In figure 13-47 of Untracht, there is a single tourmaline in a gold ring. Thus, Untracht establishes using different amounts of components in the compositions (which are designed to decorate the body and hang around the neck or finger) and it is merely judicious selection and routine optimization to create the piece by one of ordinary skill in the art. The results of ordinary innovation are not the subject of exclusive rights under the patent laws. (KSR INTERNATIONAL CO. v. TELEFLEX INC. ET AL. 550 U. S. ____ (2007))

Conclusion

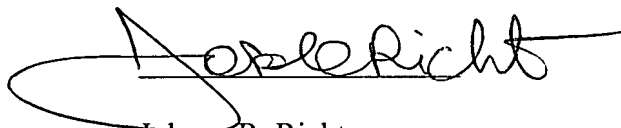
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ernst Arnold
Patent Examiner
Technology Center 1600
Art Unit 1616

A handwritten signature in black ink, appearing to read "Johann R. Richter", with a large, stylized loop at the beginning.

Johann R. Richter
Supervisory Patent Examiner
Technology Center 1600